UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,835	01/30/2002	Thomas Richardson	UMICH-11	2416

23599 7590 06/02/2004

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
VIVLEMORE, TRACY ANN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,835	RICHARDSON ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 5-12, 14-17, 24-26, drawn to a method for eliminating or reducing undesired tissue via injection of a substance in a controlled release formula wherein the undesired tissue is fat and the substance is TNF-alpha, classified in class 530, subclass 300.

II. Claims 1-2, 4-12, 17, 24-26, drawn to a method for eliminating or reducing undesired tissue via injection of a substance in a controlled release formula wherein the undesired tissue is fat and the substance is a peptide, classified in class 530, subclass 300.

III. Claims 1-2, 4-12, 17, 24-26, drawn to a method for eliminating or reducing undesired tissue via injection of a substance in a controlled release formula wherein the undesired tissue is fat and the substance is a nucleic acid, classified in class 514, subclass 44.

IV. Claims 1-2, 4-12, 17, 24-26, drawn to a method for eliminating or reducing undesired tissue via injection of a substance in a controlled release formula wherein the undesired tissue is fat and the substance is a small molecule, classified in class 424, subclass 252.

V. Claims 1,5,7,9,11,13,17, 24-26, drawn to a method for eliminating or reducing undesired tissue via injection of a controlled release formula

wherein the undesired tissue is pathologic hyperplasia, classified in class 435, subclass 1.1.

VI. Claims 1,5,7,9,11,13,17, 24-26, drawn to a method for eliminating or reducing undesired tissue via injection of a controlled release formula wherein the undesired tissue is benign tumor, classified in class 435, subclass 1.1.

VII. Claims 1,5,7,9,11,13,17, 24-26, drawn to a method for eliminating or reducing undesired tissue via injection of a controlled release formula wherein the undesired tissue is neointimal thickened vasculature, classified in class 435, subclass 1.1.

VIII. Claims 1,5,7,9,11,13,17, 24-26, drawn to a method for eliminating or reducing undesired tissue via injection of a controlled release formula wherein the undesired tissue is mole, classified in class 435, subclass 1.1.

IX. Claims 1,5,7,9,11,13,17, 24-26, drawn to a method for eliminating or reducing undesired tissue via injection of a controlled release formula wherein the undesired tissue is hair tissue, classified in class 435, subclass 1.1.

X. Claims 1, 24-27, drawn to a method for eliminating or reducing undesired tissue via injection of a substance in a controlled release formula wherein the undesired tissue is bone, classified in class 435, subclass 1.1.

XI. Claims 18-23, 28-30, drawn to a method for eliminating or reducing undesired tissue via injection of a controlled release formula to weaken or

hinder tissue formation followed by removal of the tissue via other means wherein the undesired tissue is fat, classified in class 435, subclass 1.1.

XII. Claims 18, 20-23, 28-31, drawn to a method for eliminating or reducing undesired tissue via injection of a controlled release formula to weaken or hinder tissue formation followed by removal of the tissue via other means wherein the undesired tissue is bone, classified in class 435, subclass 1.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Each invention operates using a different class of molecules as the substance of interest. Invention I operates to reduce or eliminate fat tissue using TNF-alpha, invention II operates to reduce or eliminate fat tissue using a peptide, invention III operates to reduce or eliminate fat tissue using a nucleic acid and invention IV operates to reduce or eliminate fat tissue using a small molecule.

3. Inventions V, VI, VII, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Each invention functions to reduce or eliminate a distinct type of tissue. The function of

invention V is to reduce or eliminate pathological hyperplasia. The function of invention VI is to reduce or eliminate benign tumor. The function of invention VII is to reduce or eliminate neointimal thickened vasculature. The function of invention VII is to reduce or eliminate mole tissue. The function of invention IX is to reduce or eliminate hair tissue.

4. The group of inventions I-IV and the group of inventions V-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of the inventions of groups I-IV is to reduce or eliminate fat tissue. The function of the inventions of groups V-IX is to reduce or eliminate types of tissue other than fat.

5. The group of inventions I-IV and invention X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of the inventions of groups I-IV is to reduce or eliminate fat tissue while the effect of invention X is to reduce or eliminate bone tissue.

Claim 1 link(s) inventions I-X. Claims 5, 7, 9, 11, 17, 24-26 are generic to inventions I-X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable

linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. The group of inventions I-IV and invention XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The inventions of groups I-IV operate by eliminating or reducing fat tissue via injection of a controlled release formula while invention XI operates by eliminating or reducing fat tissue using a controlled release formula to hinder or weaken the tissue coupled with removal of the tissue by other means.

7. The group of inventions I-IV and inventions XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The inventions of groups I-IV operate by eliminating or reducing fat tissue via injection of a controlled release formula while invention XII operates by

eliminating or reducing bone tissue using a controlled release formula to hinder or weaken the tissue coupled with removal of the tissue by other means.

8. The group of inventions V-IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of the inventions of groups V-IX is to reduce or eliminate different types of tissue such as pathological hyperplasia, benign tumor, neointimal thickened vasculature, mole tissue or hair tissue while the effect of invention X is to reduce or eliminate bone tissue.

9. The group of inventions V-IX and invention XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The group of inventions V-IX operate by using a controlled release formula to eliminate or reduce undesired tissue while invention XI operates by eliminating or reducing fat tissue using a controlled release formula to hinder or weaken the tissue coupled with removal of the tissue by other means.

10. The group of inventions V-IX and invention XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The group of inventions V-IX operate by using a controlled release

formula to eliminate or reduce undesired tissue while invention XII operates by eliminating or reducing bone tissue using a controlled release formula to hinder or weaken the tissue coupled with removal of the tissue by other means.

11. Inventions X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The effect of invention X is to reduce or eliminate bone tissue while the effect of invention XI is to reduce or eliminate fat tissue.

12. Inventions X and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention X operates by eliminating or reducing bone tissue via injection of a controlled release formula while invention XII operates by eliminating or reducing bone tissue using a controlled release formula to hinder or weaken the tissue coupled with removal of the tissue by other means.

13. Inventions XI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of

invention XI is to reduce or eliminate fat tissue while the function of invention XII is to reduce or eliminate bone tissue.

14. Claim 18 link(s) inventions XI and XII. Claims 20-23 and 28-30 are generic to inventions XI and XII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 18. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

15. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Species elections

This application contains claims directed to the following patentably distinct species of the claimed invention:

If invention II is elected, applicant must further elect one of the following: a cytokine regulatory agent, a protein affecting fat metabolism, leptin, orexin, prolactin, brefeldin A, a peptide having functionality which kills fat cells, a beta-adrenergic stimulator, an alpha-2 adrenergic inhibitor.

If invention III is elected, applicant must further elect one of the following: an antisense RNA molecule which knocks out the specific activity of a protein needed for fat cell maintenance, a DNA either in the form of plasmid or virus which induces the expression of apoptosis-inducing factors.

If invention IV is elected, applicant must further elect one of the following: a drug that kills fat cells, methotrexate, bromo-deoxyuridine, actinomycin D, nocodazole, brefeldin A.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TV
May 26, 2004

Tracy Vivlemore
Examiner
Art Unit 1635

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER